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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,393	11/21/2006	Naoko Horikoshi	4439-4045	3674

27123 7590 07/30/2009

MORGAN & FINNEGAN Transition Team
C/O Locke Lord Bissell & Liddell
3 WORLD FINANCIAL CENTER
NEW YORK, NY 10281-2101

EXAMINER
SHAHNAN SHAH, KHATOL S

ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
07/30/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Shopkins@Lockelord.com
OWalker@Lockelord.com

Office Action Summary	Application No.	Applicant(s)	
	10/584,393	HORIKOSHI ET AL.	
	Examiner	Art Unit	
	Khatol S. Shahnan-Shah	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *5-8 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,9-16 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 June 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/23/06, 7/18/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' amendment of 4/24/2009 is acknowledged. Claims 9-18 have been amended.

Status of Claims

2. Claims 1-18 are pending in this application.

Priority

3. Acknowledgment is made of applicants' claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed. However, no English translation has been submitted. For the purpose of the prior art priority is only given to the date of filing of PCT document 12/24/2004.

Drawings

4. The drawings submitted 06/23/2006 are objected to by the examiner. The figures are not clear and legible. Replacement copies are requested.

Information Disclosure Statement

5. The information disclosure statements filed 06/23/2006 and 07/18/2007 have been considered. Initialed copies are enclosed.

Specification

6. The disclosure is objected to because of the following informalities:

The use of the trademarks "Tween 20" and "UNI kit" have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. Appropriate corrections are required.

Abstract

7. There are two abstracts submitted with application on 06/23/2006. One has one page only and the other has two pages, which one page is the 371 abstract and other

page is another copy of abstract. Clarification is requested. The term “lysozyme” in the one page abstract has been spelled “Lyzocyme”. Appropriate corrections are required.

Election

8. Applicants' election with traverse of 4/24/2009 is acknowledged. Applicants have elected species *Listeria monocytogenes* and primers disclosed in SEQ ID NO: 5 and SEQ ID NO: 6 The traversal is on the ground(s) that applicants respectfully assert that in accordance with MPEP 803.04, the required election of primers selected from ten very short nucleotide sequences (SEQ ID NOs: 1 to 10) should be reconsidered and waives from the requirements of 37 CFR 1.141 in recognition of the "Director's" desire to promote and aid the biotechnology industry. At the very least, the primers in SEQ ID NOs: 1 to 6 should be examined together for the merits because as discussed *supra* the present invention is directed to multiple microorganisms' detection in a single operation. This is not found persuasive because as explained in the restriction requirement, the species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons Because they are drawn to physically and structurally distinct products organism and SEQ ID NOS. The requirement is still deemed proper and is therefore made FINAL. Claims 1-4, 9-16 and 18 are under consideration. Claims 5-8 and 17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claim Objections

9. Claims 11 and 13 are objected to because of the following informalities: The term “bacteriocin” is spelled “bacteriosin” in the claims. Appropriate corrections are required.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-4, 9-16 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "two or more organisms having different properties in foods", it not clear what applicants intend in said recitation. Are these organisms having different properties in general or they only have different properties in foods?

Claim 1 recites "with high sensitivity comparable or even superior to official methods", it not clear what applicants intend in said recitation. What constitute the official methods?

Claim 2 recites "under a culture condition", it not clear what applicants intend in said recitation. What constitute this culture condition?

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claim 1, 2, 3, 4, 11, 15, 16 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Aznar et al. (Systematic and Applied Microbiology, vol.25, pp. 109-119, 2002) prior art of record applicants' 1449.

The claims are drawn to a method of multiple microorganism detection which is a method for detecting two or more microorganisms having different properties in foods, with high sensitivity comparable or even superior to official methods, by amplifying a plurality of target genes with a single PCR reaction tube and analyzing the same, comprising the following steps:(A) a step for extracting DNA of the target microorganisms to be detected, by treating at least with a lytic enzyme and/or bacteriocin having lytic activity, a surfactant and a protein denaturant; and (B) a step for performing Multiplex PCR by mixing a primer specific to the target microorganisms to be detected.

Aznar et al. teach a total of nine pairs of primers, seven previously published and two newly developed, have been assayed for PCR detection of *Listeria monocytogenes* in food. They have been tested for specificity on a total of 72 strains including reference and food isolates belonging to *L. monocytogenes* and other species in the genus. (see abstract). Chromosomal DNA was extracted by the guanidium thio-cyanate i.e. a protein denaturant (see page 110 DNA isolation). Aznar et al. teach detecting two or more microorganisms having different properties (see table 1). Aznar et al. SEQ ID NO: 5 and SEQ ID NO: 6 (see table 2). Aznar et al. teach edible meat and processed meat products (see table 1). Aznar et al. teach culture enrichment after 24 hour of culture (see page 110 growth conditions). The prior anticipates the above claims.

14. Claim 1, 11 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Brasher et al. (Current Microbiology vol.37, pp. 101-107, 1998) prior art of record applicants' 1449.

The claims are drawn to a method of multiple microorganism detection which is a method for detecting two or more microorganisms having different properties in foods, with high sensitivity comparable or even superior to official methods, by amplifying a plurality of target genes with a single PCR reaction tube and analyzing the same, comprising the following steps:(A) a step for extracting DNA of the target

microorganisms to be detected, by treating at least with a lytic enzyme and/or bacteriocin having lytic activity, a surfactant and a protein denaturant; and (B) a step for performing Multiplex PCR by mixing a primer specific to the target microorganisms to be detected.

Brasher et al. teach a sensitive and rapid method for detecting Salmonella, Vibrio, Escherichia coli and other bacteria which cause food poisoning was developed. In this method, an oligonucleotide primer for five specific genes for each bacterium is used to amplify the five target genes through a single PCR, and it is suggested that this method can be applied to monitoring of pathogens as it is more sensitive and faster than detection using ordinary cultures (see abstract). Brasher et al. teach Multiplex PCR amplification of *uidA, cth, invA, ctx,* and *tl* genes was developed enabling simultaneous detection in shellfish of *Escherichia coli,* an indicator of fecal contamination and microbial pathogens, *Salmonella typhimurium, Vibrio vulnificus, V. cholerae,* and V. *parahaemolyticus,* respectively. Each of the five pairs of oligonucleotide primers was found to support PCR amplifications of only its targeted gene (see abstract). Brasher et al. teach a lytic enzyme (ptroteinase K) and depositing DNA by alcohol precipitation (see material and methods, page 102).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claim 1-4, 9-16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aznar et al. (Systematic and Applied Microbiology, vol.25, pp. 109-119, 2002) prior art of record applicants' 1449.

The claims are drawn to a method of multiple microorganism detection which is a method for detecting two or more microorganisms having different properties in foods, with high sensitivity comparable or even superior to official methods, by amplifying a plurality of target genes with a single PCR reaction tube and analyzing the same, comprising the following steps:(A) a step for extracting DNA of the target microorganisms to be detected, by treating at least with a lytic enzyme and/or bacteriocin having lytic activity, a surfactant and a protein denaturant; and (B) a step for performing Multiplex PCR by mixing a primer specific to the target microorganisms to be detected.

Aznar et al. teach a total of nine pairs of primers, seven previously published and two newly developed, have been assayed for PCR detection of *Listeria monocytogenes* in food. They have been tested for specificity on a total of 72 strains including reference and food isolates belonging to *L. monocytogenes* and other species in the genus. (see abstract). Chromosomal DNA was extracted by the guanidium thio-cyanate i.e. a protein denaturant (see page 110 DNA isolation). Aznar et al. teach detecting two or more microorganisms having different properties (see table 1). Aznar et al. SEQ ID NO: 5 and SEQ ID NO: 6 (see table 2). Aznar et al. teach edible meat and processed meat products (see table 1). Aznar et al. teach culture enrichment after 24 hour of culture (see page 110 growth conditions). The prior anticipates the above claims. Aznar et al. do not teach certain limitations such pH, medium components or chemicals used to lyse the microorganism before DNA extraction. These limitations are considered experiment parameters and it would have been prima facie obvious to one of ordinary skill in the art to develop such conditions. Also, one of ordinary skill in the art would have been motivated to by teaching of Aznar et al. to optimize the culture media and pH to obtain the best results for a Multiplex PCR assay.

Status of the Claims

17. No claims are allowed.

Conclusion

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S. Shahnan-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on Mon, Wed 12:30-6:30 pm, Thur-Fri 12:30-4:30pm pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert B. Mondesi can be reached on (571)-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Khatol S Shahnan-Shah/
Examiner, Art Unit 1645

July 22, 2009

/Robert B Mondesi/
Supervisory Patent Examiner, Art Unit 1645